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EXAMINER

BHAT, NARAYAN KAMESHWAR

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1634

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,928	Applicant(s) SQUIRRELL ET AL.	
	Examiner NARAYAN K. BHAT	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/27/2006 & 5/14/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This office action is written in reply to Applicant's correspondence filed regarding restriction April 23, 2008, wherein claims 2-17 were amended.
2. Applicant's election of group I claims 1-17 in the reply filed on April 23, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 18-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of group II and III there being no allowable generic or linking claim.
4. Claims 1-24 are pending in this application and claims 1-17 are under examination.

Note

5. The numbers for the withdrawn claims in the papers submitted on April 23, 2008 are 28-24 and Examiner assumes to be claims 18-24 (Remarks, pg. 6, paragraph 1).

Claim Interpretation

35 U.S.C. 112, sixth paragraph

6. Claims 1, 4, 8-13 are written using means-plus- function language. 'The M PEP § 2181-2184 provides guidance for claim evaluation and examination under 35 U.S.C. 112, Sixth Paragraph as set forth below:

The USPTO must apply 35 U.S.C. 112, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, in light of and consistent with the written description of the invention in the application. See *Donaldson*, 16 F.3d at 1194, and 29 USPQ2d at 1850 (stating that 35 U.S.C. 112, sixth paragraph "merely sets a limit on how broadly the PTO may construe means-plus-function language under the rubric of reasonable interpretation". The Federal Circuit has held that applicants (and reexamination patentees) before the USPTO have the opportunity and the obligation to define their inventions precisely during proceedings before the PTO. See *In re Morris*, 127 F.3d 1048, 1056-57, 44 USPQ2d 1023, 1029-30 (Fed. Cir. 1997).

A claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for" or "step for; "
- (B) the "means for" or "step for" must be modified by functional language; and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material, or acts for achieving the specified function. (see MPEP § 2181(I)).

7. In the instant case the "means for" as recited in claims 9, 11 12 and 13 does not meet the third criteria of the 3-prog analysis, viz., the phrase "means for" must not be modified by sufficient structure, material or acts for achieving the specified function. For example in claim 9, "means for" attracting the complex is modified by structure, viz., a magnet. Similarly in claims 12 and 13, "means for physical processing" is modified by

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an act, viz., heating the contents of the chamber or sonicating the contents respectively. Therefore claims 9 and 11-13 will not be interpreted in light of the “means for” disclosed in the specification.

8. The “means for removeably attaching to the functional component” as recited in claim 1 (line 5) meet the three-prong test and therefore will be interpreted in light of the “means for removeably attaching to the functional component” disclosed in the specification. The instant specification defines the means as fork (see instant specification, USPGPUB NO. paragraph 0099) or its functional equivalent.

9. The “means for moving the platform” as recited in claim 1 (line 8) meet the three-prong test and therefore will be interpreted in light of the “means for moving the platform” disclosed in the specification. The instant specification defines the means as stepper motor and a drive belt (see instant specification, USPGPUB NO. paragraph 0099) or its functional equivalent.

10. The “means for raising or lowering the arm in a substantially vertical direction” as recited in claim 4 meet the three-prong test and therefore will be interpreted in light of the “means for raising or lowering the arm in a substantially vertical direction” disclosed in the specification. The instant specification defines the means as motor attached to a drive belt and controlled by a linear actuator (see instant specification, USPGPUB NO. paragraph 0099) or its functional equivalent.

11. The “means for heating” as recited in claim 12 meet the three-prong test and therefore will be interpreted in light of the “means for heating” disclosed in the specification. The instant specification defines the means as heating element (see

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instant specification, USPGPUB NO. paragraph 0014) or its functional equivalent.

12. The “means for sonicating” as recited in claim 13 meet the three-prong test and therefore will be interpreted in light of the “means for sonicating” disclosed in the specification. The instant specification defines the means as a sonicator (see instant specification, USPGPUB NO. paragraph 0014) or its functional equivalent.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 3-5, 11, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Leighton et al (WO 99/44063 published Feb. 24, 1999).

Regarding claim 1, Leighton et al teaches an apparatus comprising: (i) a platform (Fig. 13, # 110) comprising: (a) a chamber suitable for receiving a sample (Fig. 13, # 134); (b) a functional component (Fig. 13, # 132); (ii) an arm (pg. 7, line 15) and (iii) a shaft drive (Fig. 13, # 106).

Leighton teaches an apparatus comprising a bench, i.e., platform (Fig. 13, # 110, pg. 13, line 25) and contains a container, i.e., a chamber in the tray for receiving the sample (Fig. 13, Tray- # 134, and pg. 13, lines 29-30). Leighton et al also teaches platform contains a tray comprising tissue sample (Fig. 13, # 132) and is the functional

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component of the platform. Leighton et al also teaches an arm and a joint capable of being raised or lowered (Fig. 9, # 60, pg. 7, lines 12-19) and further teaches a clamp means for removeably attaching the tissue sample (i.e., a functional component) such that the functional component may be raised or lowered with the arm (Fig. 9, # 56, pg. 7, lines 12-19). Leighton et al also teaches a shaft drive, a means for moving the platform such that any chamber or functional component may be aligned with respect to the arm (Fig. 13, # 106, pg. 13, lines 24-25).

Regarding claim 3, Leighton et al teaches an arm that mechanically removeably attaches to the functional component (Fig. 9, # 56, pg. 7, lines 12-19).

Regarding claim 4, Leighton et al teaches an apparatus comprising an arm and a joint capable of raising and lowering the arm in a substantial vertical direction (Fig. 9, Joint # 60, pg. 7, lines 12-19).

Regarding claim 5, Leighton et al teaches a tissue sample (i.e., a functional component) in a container (pg. 13, lines 28-30) for isolating DNA and RNA analyte (pg. 13, lines 7-10).

Regarding claim 11, Leighton et al teaches an apparatus comprising a microtome for physical processing means for cutting and separating tissue sample (pg. 3, line 26).

Regarding claim 15, Leighton et al teaches a container containing a liquid medium (pg. 13, lines 29-30), which can be configured to comprise a pre-dispensed reagent. It is noted that a chamber comprising a pre-dispensed reagent is the recitation of intended use of the apparatus.

Regarding claim 17, Leighton et al teaches an apparatus for obtaining sample to

isolate RNA and DNA for PCR (pg. 13, lines 7-11), thus teaching a method of using the apparatus for processing of a sample prior to nucleic acid amplification.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leighton et al (WO 99/44063 published Feb. 24, 1999) in view of Ammann et al (USPGPUB NO. 2002/0028489 published Mar. 7, 2002).

Claim 2 is dependent from claim 1. Teachings of Leighton et al regarding claim 1, are described in this office action in section 14.

Regarding claim 2, Leighton et al teaches a platform, which is rectangular in

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shape (Fig. 13, # 110) comprising a chamber and a functional component thus teaching all the structural features recited in the claim but is silent about the platform being circular. However, a circular platform was known in the art at the time of the claimed invention was made as taught by Ammann et al, who teaches a circular platform to hold different reaction receptacles, stations and trays (Fig. 4, platform # 250 and paragraphs 0022 and 0107). Ammann et al also teaches that circular platform comprising different stations allows the efficient space utilization and perform parallel operations of different assay simultaneously thereby facilitating efficient high throughput operation (paragraph 0022).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the platform of Leighton et al and include circular platform of Ammann et al with a reasonable expectation of success.

An artisan would have been motivated to modify the platform of Leighton et al and include circular platform of Ammann et al with the expected benefit of having circular platform comprising different stations allowing the efficient space utilization and performing parallel operations of different assay simultaneously thereby facilitating efficient high throughput operation as taught by Ammann et al (paragraph 0022).

18. Claims 1, 5-11, 13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leighton et al (WO 99/44063 published Feb. 24, 1999) in view of Smith et al (USPN 6,027,945 issued Feb. 22, 2000).

Claims 5, 11 and 15 are dependent from claim 1. Claims 6-10 are dependent

from claim 5. Claim 16 is dependent from claim 15. Teachings of Leighton et al regarding claims 1, 5 and 15 are described in this office action in section 14.

Regarding claims 6-10 and 16, Leighton et al teaches an apparatus for processing a sample to isolate nucleic acids, i.e., analyte and further teaches extraction of DNA and RNA from the tissue sections (Fig. 10C, pg. 9, lines 21-23). Leighton et al are silent about extraction protocol, especially about solid phase binding material capable of forming complex with the analyte. However, solid phase binding material capable of forming complex with the analyte was known in the art at the time of the claimed invention was made as taught by Smith et al.

Smith et al teaches solid phase binding material capable of forming complex with the DNA analyte is silica magnetic material (Abstract and column 6, lines 19-20, limitations of claims 6-7 and 16) and further teaches that means of attracting DNA analyte -silica magnetic particle complex is a magnet (Abstract and column 12, lines 40-50, limitations of claims 8-9). Smith et al also teaches that tissue sample, i.e., functional component, is used for isolating DNA using silica magnetic particles in a container (Abstract and column 9, lines 60-67, column 10, lines 1-5) and the magnet is adjacent to the container, thus teaching that the tissue is the sheath, which provides an interface between the magnet (i.e., the means for attracting the complex) and the DNA-silica-magnetic particle complex (column 12, lines 40-50, limitation of claim 10).

Regarding claim 13, Smith et al teaches a sonicator, a means for sonicating the contents of the container.

Smith et al also teaches that silica magnetic particle provides convenient and

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efficient means for isolating biological target material of interest and sufficiently free of contaminating material, which can interfere with further analyses and is amenable to being automated (Abstract and column 7, lines 3-30)

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the sample processing apparatus of Leighton et al and include solid phase binding material of Smith et al with a reasonable expectation of success.

An artisan would have been motivated to modify the sample processing apparatus of Leighton et al and include solid phase binding material of Smith et al with the expected benefit of having silica magnetic particle providing convenient and efficient means for isolating biological target material of interest and having an analyte sufficiently free of contaminating material, which can interfere with further analyses and is amenable to being automated as taught by Smith et al (Abstract and column 7, lines 3-30), thus providing high quality DNA samples needed for genotyping to correlate with the phenotype in the device of Leighton et al.

19. Claims 1, 11-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leighton et al (WO 99/44063 published Feb. 24, 1999) in view of Lee (WO 98 published Jun. 11, 1998, cited in the IDS filed 3/27/2006).

Claims 11 and 14 are dependent from claim 1. Claim 12 is dependent from claim 11. Teachings of Leighton et al regarding claim 1 are described in this office action in sections 14.

Regarding claims 12 and 14, Leighton et al teaches an apparatus for processing a sample and further teaches containers (i.e., chambers), but are silent about coating of the chamber with an electrically conducting polymer and a means for heating the contents of a chamber. However, coating of the chamber with an electrically conducting polymer and a means for heating the contents of a chamber were known in the art at the time of the claimed invention was made as taught by Lee, who teaches a reaction vessel, i.e., a chamber (Fig. 1, # 1) coated with an electrically conducting polymer (Fig. 1, # 3, pg. 11, lines 1-5, limitation of claim 14). Lee also teaches a heating element, a means for heating the contents of a chamber (pg. 4, lines 3-5, limitation of claim 12).

Lee also teaches that electrically conducting polymer coated reaction vessels provides an efficient system for rapid heating and cooling of reactions and temperature of the individual vessels is controlled independently of one another with their own profile for carrying out different reactions requiring different operating temperatures (pg. 5, lines 21-31).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the sample processing apparatus of Leighton et al and include chambers of Lee with a reasonable expectation of success.

An artisan would have been motivated to modify the sample processing apparatus of Leighton et al and include chambers of Lee with the expected benefit of having electrically conducting polymer coated reaction vessels providing an efficient system for rapid heating and cooling of reactions and having temperature of the individual vessels controlled independently of one another with their own profile for

carrying out different reactions requiring different operating temperatures (pg. 5, lines 21-31). Lee providing the physical processing means would be very beneficial to disrupt the cells from tissue sections obtained using the device of Leighton et al and to further isolate DNA using solid phase material of Smith et al to have high quality DNA samples needed for genotyping to correlate with the phenotype as championed by Leighton et al (pg. 12, lines 29-37).

Conclusion

20. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

Narayan K. Bhat, Ph. D.

/BJ Forman/

Primary Examiner, Art Unit 1634